### UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

IN RE DDAVP INDIRECT PURCHASER ANTITRUST LITIGATION	: No. 05 Civ. 2237 (CS)
	: ORAL ARGUMENT REQUESTED

THIS DOCUMENT RELATES TO: ALL ACTIONS

MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF DEFENDANTS' JOINT MOTION TO DISMISS THE INDIRECT PURCHASER PLAINTIFFS' AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

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#### **INTRODUCTION**

Plaintiffs, so-called indirect purchasers of desmopressin acetate ("DDAVP") tablets, filed this action against defendants Ferring B.V. and Ferring Pharmaceuticals, Inc. (collectively, "Ferring") and Aventis Pharmaceuticals, Inc. ("Aventis") shortly after this Court (Brieant, J.) held that a Ferring patent for DDAVP tablets was unenforceable due to inequitable conduct before the Patent and Trademark Office ("PTO"). Judge Brieant dismissed the action in 2006, but after the Second Circuit remanded a parallel case brought by direct purchasers of DDAVP, *In re DDAVP Direct Purchaser Antitrust Litigation*, 585 F.3d 677 (2d Cir. 2009), the parties jointly moved to remand the case to this Court for further proceedings. This Court subsequently vacated the judgment of dismissal, granted plaintiffs an opportunity to amend their complaint, and directed defendants to file any further motions to dismiss by September 16.

As set forth herein, plaintiffs' new Amended Consolidated Class Action Complaint ("Complaint") is legally deficient on several grounds. *First*, plaintiffs' sole federal claim (an injunction claim for violation of the Sherman Act) should be dismissed because the alleged conduct ceased more than five years ago and *cannot* be repeated or threaten any prospective harm. *Second*, all of plaintiffs' state law claims are preempted either by federal patent or federal food-and-drug law. *Third*, plaintiffs lack standing to assert state law claims under the laws of states where they do not reside. *Finally*, many of plaintiffs' state law claims are substantively deficient.

#### **BACKGROUND**

As the Second Circuit recognized in the direct purchasers' appeal, the "linchpin" of this case is an attack upon Ferring's '398 patent, which covered DDAVP tablets. *See* 585 F.3d at 682. In 2002, after Barr Laboratories, Inc. ("Barr"), a generic pharmaceutical company, filed an

application seeking Food and Drug Administration ("FDA") approval for a generic version of DDAVP tablets, Ferring and Aventis (the licensee of the '398 patent) filed a patent infringement suit, charging that Barr infringed the '398 patent. Compl. ¶ 85.

On February 7, 2005, Judge Charles L. Brieant found that the '398 patent was unenforceable due to inequitable conduct before the PTO -- specifically, he ruled that Ferring had failed to disclose certain prior relationships between Ferring and some of the scientists who submitted affidavits supporting the patent application. Ferring B.V. v. Barr Labs., Inc., No. 02-cv-9851 (CLB), 2005 WL 437981, at \*9 (S.D.N.Y. Feb. 7, 2005). Judge Brieant did not find that the '398 patent was procured by fraud on the PTO, nor that the patent was invalid. *Id.* To the contrary, in denying Barr's subsequent motion for attorney's fees, the Court explained that it "never found conduct rising to the level of fraud." Oral Argument Transcript at 34, Ferring B.V. v. Barr Labs, Inc., No. 02-cv-9851 (CLB) (Mar. 1, 2007). On February 15, 2006, a split panel of the Federal Circuit affirmed Judge Brieant's ruling that the '398 patent was unenforceable due to inequitable conduct. Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181 (Fed. Cir. 2006), cert. denied, 127 S. Ct. 515 (2006) ("Ferring II"). Judge Newman filed a vigorous dissent, id. at 1195-1205, concluding that defendants' acts did not even rise to the level of inequitable conduct.<sup>1</sup>

In 2005, shortly after Judge Brieant held the '398 patent to be unenforceable, putative classes of direct and indirect purchaser plaintiffs filed substantially identical actions against

<sup>&</sup>lt;sup>1</sup> The Federal Circuit, sitting *en banc*, has subsequently modified the standard for determining inequitable conduct and rejected the very test it applied to find inequitable conduct in Ferring II. See Therasense, Inc. v. Becton, Dickinson & Co., \_\_\_ F.3d \_\_, No. 2008–1511, 2011 WL 2028255, at \*25 (Fed. Cir. May 25, 2011) ("tighten[ing]" the standard for inequitable conduct by requiring separate showings of materiality and intent to deceive the PTO, and explicitly abolishing a "sliding scale" analysis of materiality and intent).

Ferring and Aventis, which were consolidated before Judge Brieant. Both the direct and the indirect purchaser plaintiffs alleged that Ferring and/or Aventis acted unlawfully by:

(i) obtaining the '398 patent through fraud or inequitable conduct before the PTO; (ii) improperly listing the '398 patent in the FDA's "Orange Book"; (iii) prosecuting baseless patent infringement lawsuits; and (iv) filing a "sham" citizen petition asking FDA to require additional testing before approving generic versions of DDAVP tablets.

Judge Brieant dismissed the direct and indirect purchasers' federal antitrust claims with prejudice, and dismissed the indirect purchasers' state law claims without prejudice. *In re DDAVP Antitrust Litig.*, No. 05-cv-2237 (CLB), slip op. at 15 (S.D.N.Y. Nov. 2, 2006). The Court ruled that: (1) the complaints failed to plead facts adequate to state a claim for fraud on the PTO, a necessary predicate for their antitrust claims, and (2) only competitors, and not purchasers, had standing to bring the antitrust claims alleged by plaintiffs. *Id.* at 8, 12, 15. The Second Circuit reversed the summary judgment in 2009, although it did *not* address the grounds for dismissing the indirect purchaser complaint that Judge Brieant had not addressed. By agreement of the parties, the indirect purchaser action was remanded to this Court for further proceedings.

### **PLAINTIFFS' ALLEGATIONS**

Like the direct purchaser complaint addressed by the Second Circuit, plaintiffs' current Complaint alleges that Ferring and/or Aventis acted unlawfully by: (1) procuring the '398 patent through fraud and/or inequitable conduct before the PTO; (2) improperly listing the '398 patent in the Orange Book because it had been fraudulently obtained; (3) instituting "sham" patent infringement litigation against potential generic competitors to enforce the allegedly fraudulent patent; and (4) filing a "sham" citizen petition with FDA in an effort to further delay FDA

approval of generic DDAVP tablets. Compl. ¶ 2. While the direct purchasers sought recovery only under the federal antitrust laws, indirect purchaser plaintiffs here seek injunctive relief under federal antitrust law and damages under state laws.

Specifically, plaintiffs seek to represent a class consisting of all persons and entities who indirectly purchased DDAVP tablets. *Id.* ¶ 124. In Count I, plaintiffs seek injunctive and equitable relief under Section 16 of the Clayton Act for an alleged violation of Section 2 of the Sherman Act. Count II seeks damages under various state antitrust and consumer protection laws, and Count III seeks restitution and disgorgement under state unjust enrichment laws.

#### **LEGAL STANDARD**

This motion is brought under Federal Rule of Civil Procedure 12(b)(1) for lack of standing, and under Rule 12(b)(6) for failure to state a claim upon which relief can be granted. To survive a motion to dismiss, a complaint must provide more than "labels and conclusions" and "a formulaic recitation of the elements of a cause of action." *Bell Atlantic Corp. v.*Twombly, 550 U.S. 544, 555 (2007); *see also Ashcroft v. Iqbal*, 129 S.Ct. 1937, 1949 (2009). A plaintiff's allegations "must be enough to raise [the plaintiff's] right to relief above the speculative level," *Twombly*, 550 U.S. at 555 (citations omitted), and must include "enough facts to state a claim to relief that is plausible on its face." *Id.* at 570; *Iqbal*, 129 S. Ct. at 1949.

#### <u>ARGUMENT</u>

## I. PLAINTIFFS CANNOT STATE A CLAIM FOR INJUNCTIVE OR EQUITABLE RELIEF

As an apparent predicate for seeking federal jurisdiction over plaintiffs' state law damage claims, Count I of the Complaint purports to seek "injunctive relief under Section 16 of the Clayton Act . . . to remedy the anti-competitive market effects caused by the unlawful conduct of

Defendants . . .. " Compl. ¶ 138. But section 16 of the Clayton Act only authorizes suits for injunctive relief when there is "threatened loss or damage." 15 U.S.C. § 26 (emphasis added). Here, however, there could not possibly be any "threatened" loss or damage to plaintiffs, because the '398 patent has already been held to be unenforceable, and that ruling has been final for many years.

The entire premise of the Complaint is that defendants took actions to improperly create and maintain a monopoly by procuring and listing the '398 patent *in the late 1980s and early 1990s*; enforcing the patent *during 2002-2005*; and filing a citizen petition that was resolved by the FDA *on July 1, 2005*. Compl. ¶¶ 54-119. The allegedly improper enforcement efforts ceased irrevocably on February 7, 2005, when the patent was held to be unenforceable. Generic competitors, unconstrained by the '398 patent, entered the market in 2005-06.

It is well-established that injunctions may be granted only where necessary to prevent ongoing or prospective harm. Where, as here, all alleged conduct ended long ago and could not possibly create a risk of recurrence in the future, injunctive relief may not be granted. *See, e.g., United States v. Borden Co.*, 347 U.S. 514, 520 (1954) (holding that injunctions may only be granted where "there exists some cognizable danger of recurrent violation") (internal quotation marks omitted); *United States v. Or. State Med. Soc'y*, 343 U.S. 326, 333 (1952) (observing that the "sole function of an action for injunction is to forestall future violations"); *Chance v. Bd. of Exam'rs*, 561 F.2d 1079, 1092 n.25 (2d Cir. 1977) (quoting *Milk Wagon Drivers Union, Local 753 v. Meadowmoor Dairies*, 312 U.S. 287, 298-99 (1941) (an injunction is "justified only by the [wrongdoing] that induced it and only so long as it counteracts a continuing [violation]")).

Even in theory, any threatened harm or loss from defendants' purportedly unlawful efforts to obtain and enforce the '398 patent and to delay generic competition through petitioning

the FDA ceased more than five years ago. There is no possibility that the '398 patent could be revived. There is no possibility that the citizen petition could be revived. Under these circumstances, any claim for injunctive relief is baseless. *See In re G-Fees Antitrust Litig.*, 584 F. Supp. 2d 26, 35 (D.D.C. 2008) (dismissing claim for injunctive relief because plaintiffs' claim arose from a past injury as to which damages would be realized in the future, not from the threat of future injury required for injunctive relief); *In re Nifedipine Antitrust Litig.*, 335 F. Supp. 2d 6, 19 (D.D.C. 2004) ("In the context of injunctive relief, however, lingering monetary injury, without any ongoing threat of recurrent violations [to the plaintiffs], is not sufficient to confer standing to seek an injunction.").

### II. ALL OF PLAINTIFFS' STATE LAW CLAIMS ARE PREEMPTED BY FEDERAL PATENT LAW AND/OR FDA LAW

### A. Plaintiffs' Claims Premised on Conduct Before the PTO Are Preempted By Federal Patent Law

Where a plaintiff brings a state law claim that encroaches upon federal patent law, the claim is necessarily preempted. As one court has succinctly explained: "The Court must assess whether the [state] tort action is based on conduct that is protected or governed by federal patent law. If the conduct at issue is protected or governed by federal patent law, the [state] action is preempted." *Cardiovention, Inc. v. Medtronic, Inc.*, 430 F. Supp. 2d 933, 939 (D. Minn. 2006). "Just as a State cannot encroach upon the federal patent laws directly, it cannot, under some other law, such as that forbidding unfair competition, give protection of a kind that clashes with the objectives of the federal patent laws." *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 231 (1964); *see Ultra-Precision Mfg., Ltd. v. Ford Motor Co.*, 411 F.3d 1369, 1377 (Fed. Cir. 2005) (state unjust enrichment claim is preempted by federal patent law when state claim stands "as an

obstacle to the accomplishment and execution of the full purposes and objectives of Congress" (internal quotations and citations omitted)).

State law claims -- like those alleged here -- that are based on misconduct before the PTO clearly encroach upon federal patent law and are preempted by it. In *Abbott Laboratories v*. *Brennan*, 952 F.2d 1346 (Fed. Cir. 1991), the defendant-inventor sought to assert a state law abuse of process claim against the plaintiff patent-holder. Although the trial court found that Abbott Laboratories had engaged in inequitable conduct before the PTO, the Federal Circuit dismissed the state law claim and held that no "state tort action for abuse of process can be invoked as a remedy for inequitable or other unsavory conduct of parties to proceedings in the Patent and Trademark Office." *Id.* at 1355. Because federal patent law provides a remedy for wrongful conduct before the PTO, the court concluded that an "additional state action would be an inappropriate collateral intrusion on the regulatory procedures of the PTO . . . and is contrary to Congress' preemptive regulation in the area of patent law." *Id.* at 1357.

Numerous courts have held state law claims to be preempted where the claim was predicated upon alleged misconduct in obtaining a patent. *See, e.g., Semiconductor Energy Lab. Co., Ltd. v. Samsung Elecs. Co., Ltd.*, 204 F.3d 1368, 1382-83 (Fed. Cir. 2000) (state racketeering claim held to be preempted by federal patent law where the claim was based on misconduct before the PTO); *Sign-A-Way, Inc. v. Mechtronics Corp.*, No. 98-1491, 2000 WL 353151, at \*4-5 (Fed. Cir. Apr. 5, 2000) (state law contract claim is preempted because liability was based on patent holders' conduct before the PTO).

With the exception of the citizen petition allegation (which, as described below, is independently preempted by FDA law), plaintiffs' state law claims rest entirely on actions allegedly undertaken by Ferring and/or Aventis to procure and enforce the '398 patent. As the

Second Circuit recognized, the '398 patent is the "linchpin" of plaintiffs' case; except for the citizen petition allegation, *all* of plaintiffs' allegations "turn on how the '398 patent was procured." 585 F.3d at 685. The Second Circuit concluded that plaintiffs' "right to relief necessarily depends upon resolution of a substantial question of federal patent law," and that (apart from the citizen petition claim), such claims arise under federal patent law (despite being denominated "antitrust" claims). *Id*.

Based on the facts alleged, plaintiffs would have to prove that Ferring engaged in misconduct in the PTO to procure the patent in order to establish any of their claims concerning the '398 patent's procurement or enforcement. Because federal patent law unquestionably governs conduct before the PTO and provides a remedy for wrongful conduct in procuring a patent (*i.e.*, finding the unenforceable or invalid), "additional state action would be an inappropriate collateral intrusion on the regulatory procedures of the PTO." *Abbott Labs.*, 952 F.2d at 1357. As the Second Circuit recognized, plaintiffs' patent-related allegations require proof of misconduct before the PTO; accordingly, any effort to prosecute such conduct under state law is preempted by federal patent law.

Directly on point is *In re Ciprofloxacin Hydrochloride Antitrust Litigation* ("Cipro"), 363 F. Supp. 2d 514 (E.D.N.Y. 2005), *aff'd on other grounds*, 544 F.3d 1323 (2d Cir. 2008). In that case, plaintiffs asserted state law claims based on the allegedly fraudulent procurement of a patent, the subsequent listing of the patent in the Orange Book, and enforcement of the patent through litigation allegedly filed with knowledge that the patent was procured by fraud. The district court found that the state claims were preempted by federal patent law, because the claims for violating state antitrust and/or consumer protection laws did "not allege any malfeasance in the marketplace such as threats to [a generic competitor] or its customers, but

instead rest[ed] entirely upon actions that occurred before the PTO." *Id.* at 545. The court considered the act of initiating patent infringement litigation to be "directly referable" to the alleged misconduct before the PTO and thus did not involve distinct, marketplace conduct that could avoid preemption. *Id.* The court also rejected the argument that listing the patent in the Orange Book constituted conduct that would avoid preemption, holding that "[t]here was nothing in the act of listing the [] patent in the Orange Book that was itself improper." *Id.* at 546. Rather, the listing was alleged to be improper only "because [the defendant] was using it to maintain an allegedly ill-gotten patent." *Id.* The same is true of plaintiffs' allegations here.

Similarly in *Daiichi Sankyo, Inc. v. Apotex, Inc.*, No. 030937, 2009 WL 1437815 (D.N.J. May 19, 2009), the court addressed state law claims for tortious interference with contract and unjust enrichment that relied on allegations that the patent-holder fraudulently procured a patent for the drug ofloxacin, listed the patent in the Orange Book, and initiated patent infringement litigation knowing the patent was invalid due to fraud on the PTO. The court held that the state law counterclaims were preempted because "both counterclaims are, at the core, based on the same alleged fraudulent conduct before the PTO" and "[w]ithout the alleged fraud, no liability could attach" to the listing in the Orange Book or the filing of infringement litigation. *Id.* at \*9.

In another similar case, *In re K-Dur Antitrust Litigation*, MDL No. 1419, 2007 WL 5297755 (D.N.J. Mar. 1, 2007), the court addressed the issue of whether a state law "*Walker Process*-styled monopolization" claim was preempted by patent law. As in the instant case, the indirect purchaser plaintiff class there alleged that the patent-holder obtained the patent by fraud or inequitable conduct and later tried to enforce it through alleged improper listing of the patent in the *Orange Book* and sham litigation. The plaintiffs argued that while their state law claims required "consideration of conduct before the PTO, they also require[d] proof of elements

specific to antitrust claims." *Id.* at \*7. The court rejected this argument, finding that, while the plaintiffs' state law claims rested on various statutes that did "not contain identical language or identical elements of proof," all the state claims "suffer[ed] from the same defect; *i.e.*, they fundamentally rel[ied] upon evidence of fraud or 'inequitable conduct' before the PTO, or evidence derivative of those actions to satisfy their respective elements of proof." *Id.* at \*24. Further, the court held "evidence of marketplace conduct . . . [was] sorely lacking." *Id.* Because the state law claims "rely, either directly or derivatively, upon allegedly fraudulent or inequitable conduct before the PTO," the court held them to be preempted by federal patent law. *Id.* at \*25.

In earlier proceedings before Judge Brieant, plaintiffs conceded that their claims arose from misconduct before the PTO, but argued that their state claims should not be preempted because they contain "additional elements" above and beyond an allegation of patent fraud. Specifically, plaintiffs argued that because state antitrust claims require proof of "additional elements" such as "market power" and a "relevant market," they are broader than patent claims and are not preempted. But the case law that plaintiffs relied upon does not support such a broad proposition; a state claim cannot survive a preemption challenge simply because there is some element of the claim that does not involve patent misconduct. Rather, to avoid preemption, it is necessary for the plaintiff to show that "liability" can be established by proving elements apart from misconduct before the PTO -- such as wrongful conduct in the marketplace. See, e.g.,

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<sup>&</sup>lt;sup>2</sup> Some of the claims were based on state consumer fraud statutes, others on abuse of process, and others on state antitrust statutes, such as the New Jersey Antitrust Act, which requires proof of the following elements for a monopolization claim: (1) relevant geographic and product markets; (2) high probability of success in monopolization, (3) specific intent, and (4) conduct in furtherance of the monopolization attempt. *Id.* at \*24 n. 23 (citations omitted).

<sup>&</sup>lt;sup>3</sup> Before Judge Brieant (who, as noted above, did not rule on this aspect of the motion), plaintiffs relied primarily upon *Dow Chemical v. Exxon Corp.*, 139 F.3d 1470 (Fed Cir. 1998), for their argument that state law claims are not preempted if they include any "additional elements" beyond patent law misconduct. However, *Dow Chemical* merely held that where a state law claim could be proved by "marketplace" conduct involving elements that were "entirely

*Semiconductor*, 204 F.3d at 1382 (holding state RICO claims to be preempted). Here, the alleged misconduct before the PTO is a fundamental element of plaintiffs' case.

As the Second Circuit recognized, plaintiffs' patent-related claims are premised upon proving that the '398 patent was wrongfully procured through misconduct before the PTO. *See In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d at 693-94. But allegations of misconduct before the PTO may not be pursued under state law. Accordingly, all of plaintiffs' claims (other than the citizen petition allegation, which is discussed below) are preempted by federal patent law and should be dismissed.

#### B. Plaintiffs' Citizen Petition Claim Is Preempted By Federal FDA Law

Plaintiffs' only non-patent allegation contends that Ferring filed a baseless citizen petition with the FDA on February 2, 2004 in order to "further delay generic entry" by deceiving the FDA. Compl. ¶ 102. Citizen petitions are a creature of federal food and drug law; accordingly, state law challenges to a citizen petition encroach upon a unique federal regulatory scheme and are preempted. *See Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (stating that state law claims are preempted where they "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress").

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by, federal law." *Id.* at 348. The Supreme Court explained that the "conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter

different" from the elements of patent misconduct, then the claim was not preempted. 139 F.3d at 1477. In *Dow*, plaintiff alleged that the defendant had wrongfully threatened to sue others, even though the defendant knew that the targets of the threats had not actually infringed the patent. *Id.* at 1472. There are no comparable allegations of "marketplace" misconduct here. Judge Brieant did not address this issue because he dismissed the complaint on other grounds.

fraud against the [FDA], and that this authority is used by the [FDA] to achieve a somewhat delicate balance of statutory objectives." *Id.* Because the *Buckman* plaintiffs' state law claims arose from and depended upon the existence of the FDA's regulatory scheme, the Supreme Court held that state claims "would exert an extraneous pull on the scheme established by Congress" and were therefore preempted. *Id.* at 353. The citizen petition at issue in this case is an exclusive creation of federal law, *see* 21 C.F.R. § 10.30, and the authority to police citizen petitions lies exclusively with the FDA. *See id.* § 10.20. As such, plaintiffs' state law claims premised on the alleged sham citizen petition are preempted by FDA law.

The Supreme Court's recent decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009) -- while declining to find federal preemption with respect to drug *labeling* -- is fully consistent with a finding of preemption here. In *Wyeth*, the Court held that state tort claims based on Wyeth's failure to warn patients of a drug safety concern were not preempted by the federal Food Drug and Cosmetic Act ("FDCA"), because Congress intended the FDCA merely to "supplement[] the protection for consumers already provided by state regulation and common-law liability," and not to preempt state law failure-to-warn claims. *Id.* at 1195 & 1202. Unlike in *Wyeth*, where the state law tort claims were consistent with Congressional purpose, state law claims based on citizen petitions filed with the FDA would frustrate the Congressional goal of encouraging the public to supply the FDA with information regarding the safety and efficacy of drugs. Cutting off a vital source of information through the threat of state law liability would hinder the FDA's ability to carry out the purposes of the FDCA to ensure a safe and effective drug supply in the United States.<sup>4</sup>

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<sup>&</sup>lt;sup>4</sup> Desiano v. Warner-Lambert & Co., 467 F.3d 85 (2d Cir.), aff'd per curium, 552 U.S. 440 (2008), is also distinguishable from the instant case. There, the court found that state law product liability claims were not preempted, because "proof of fraud against the FDA" was not

Allowing indirect purchaser plaintiffs to bring antitrust and/or consumer protection claims attacking citizen petitions under the varying laws of fifty states and the District of Columbia would, as *Buckman* warned, "exert an extraneous pull on the scheme established by Congress" and chill the disclosure of important safety and efficacy concerns to the FDA. The FDA alone has authority to police statements made to it and plaintiffs should not be permitted to affect the FDA's exclusive responsibility for evaluating and introducing new drugs and ensuring the safety and efficacy of those drugs. Thus, the citizen petition claim, like the patent claims, is preempted, and the entire case should be dismissed.

# III. PLAINTIFFS LACK STANDING TO ASSERT ANY STATE LAW CLAIMS EXCEPT THOSE ARISING UNDER THE LAWS OF FLORIDA, ILLINOIS, AND PENNSYLVANIA

Plaintiffs lack standing to assert claims under the laws of any state other than the state in which they suffered an alleged injury (*i.e.*, the state in which each resides and purchased DDAVP). It is the "burden of the party who seeks the exercise of jurisdiction in his favor clearly to allege facts demonstrating that he is a proper party to invoke judicial resolution of the dispute." *Spencer v. Kemna*, 523 U.S. 1, 11 (1998). Plaintiffs have failed to allege facts demonstrating their standing to assert any claims other than claims under the laws of Florida, Illinois, and Pennsylvania. All other state law claims should be dismissed.

To establish standing under Article III of the Constitution, "a plaintiff must have suffered an 'injury in fact' that is 'distinct and palpable'; the injury must be fairly traceable to the challenged action; and the injury must be likely redressable by a favorable decision." *Denney v. Deutsch Bank, AG,* 443 F.3d 253, at 263 (2d Cir. 2006) (quoting *Lujan v. Defenders of Wildlife,* 

an element of the state claim, but merely part of an affirmative defense. *Id.* at 96. In contrast, in the instant case (as in *Buckman*), plaintiffs' attack on an FDA citizen petition constitutes a claim that "exist[s] solely by virtue of the FDCA" and therefore should be preempted. 531 U.S. at 353.

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504 U.S. 555, 560-61 (1992)). In a class action, the named plaintiffs "must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent." *Lewis v. Casey*, 518 U.S. 344, 357 (1996) (internal citations and quotations omitted; emphasis added); *Payton v. County of Kane*, 308 F.3d 673, 682 (7th Cir. 2002) ("[I]t bears repeating that a person cannot predicate standing on injury which he does not share. Standing cannot be acquired through the back door of a class action."). A named plaintiff must have suffered injury under *each claim* asserted, even if the claims are related. *See Lewis*, 518 U.S. at 358 n.6; *In re Salomon Analyst Level 3 Litig.*, 350 F. Supp. 2d 477, 496 (S.D.N.Y. 2000) (at least one *named* plaintiff must have standing to pursue each claim alleged).

Plaintiffs seek to pursue claims under the laws of all fifty states and the District of Columbia. Compl. ¶ 148. But the Complaint alleges that plaintiffs reside in only three states: Florida, *id*. ¶ 11, Illinois, *id*. ¶ 13, and Pennsylvania. *Id*. ¶¶ 12-14. The Complaint alleges injury to these specific individuals. *Id*. ¶¶ 15-16. The Complaint does not identify any other plaintiff residing in any other state who allegedly suffered injury.

In similar indirect purchaser pharmaceutical suits, numerous courts have concluded that the complaint *must* name a plaintiff who has been injured within each jurisdiction upon whose law the complaint relies. *See In re Flonase Antitrust Litig.*, 610 F. Supp. 2d 409, 419 (E.D. Pa. 2009) (dismissing claims of indirect purchaser health and welfare funds under the law of states where no named plaintiff resided or was injured, and ruling that plaintiffs "cannot establish standing merely by relying on claims of putative class members and must establish their own standing to assert each claim"); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 158 (E.D. Pa. 2009) (finding plaintiffs failed to allege their standing to bring claims in the majority of the

jurisdictions referenced in their complaint); *In re Ditropan XL Antitrust Litig.*, 529 F. Supp. 2d 1098, 1109 (N.D. Cal. 2007) (dismissing claims in twenty-four states because none of the named plaintiffs resided in or alleged that they personally purchased Ditropan XL in any of those states); *In re Terazosin Hydrochloride Antitrust Litig.*, 160 F. Supp. 2d 1365, 1370-72 (S.D. Fla. 2001) (dismissing state claims because the "the named plaintiffs cannot rely on unidentified persons within those states to state a claim for relief," and because "[c]lass allegations that others suffered injuries giving rise to claims add . . . nothing to the question of standing") (citation omitted).

This rule has been applied by other federal courts in New York. *See Temple v. Circuit City Stores*, Nos. 06-CV-5303(JG), 06-CV-5304(JG), 2007 WL 2790154, at \*8 (E.D.N.Y. Sept. 25, 2007) (finding that plaintiffs located in Tennessee "had no standing to bring claims for injuries under the laws of the non-Tennessee states," and therefore dismissing those claims for lack of subject matter jurisdiction); *In re Salomon Analyst Level 3 Litig.*, 350 F. Supp. 2d at 496 (dismissing claims for lack of standing where named plaintiff sought to represent plaintiffs of a distinct subclass for which no named plaintiff had been identified, and who had separate legal remedies). Numerous other courts have reached the same conclusion.<sup>5</sup>

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<sup>&</sup>lt;sup>5</sup> See, e.g., In re Packaged Ice Antitrust Litig., No. 08-MD-10952, 2011 WL 891169, at \*13 (E.D. Mich. Mar. 11, 2011) (finding that indirect purchaser plaintiffs could not establish the necessary connection to make claims of injury plausible through a conclusory allegation that they purchased ice in a number of non-specified states where they did not reside); In re Checking Account Overdraft Litig., 694 F. Supp. 2d 1302 (S.D. Fla. 2010) (dismissing antitrust, consumer protection, and unjust enrichment claims in numerous jurisdictions for failure to allege personal injury in these jurisdictions); In re Potash Antitrust Litig., 667 F. Supp. 2d 907, 923-24 (N.D. Ill. 2009) (same); In re G-Fees Antitrust Litig., 584 F. Supp. 2d 26, 35 (D.D.C. 2008) (dismissing claims arising under the laws of seventeen jurisdictions because the complaint allegations failed to support an inference that any of the named plaintiffs had been personally injured in those jurisdictions); In re Graphics Processing Units Antitrust Litig., 527 F. Supp. 2d 1011, 1026 (N.D. Cal. 2007) (dismissing state law antitrust claims of seven states because there was no named plaintiff from those states who suffered injury from defendants' claimed conduct).

Although the Complaint states that the two fund plaintiffs have beneficiaries who live in "other states" besides Pennsylvania, Compl. ¶¶ 12-14, it does not identify who those beneficiaries are, where they reside, or where they suffered an alleged injury. Cursory statements that members of organizations are located in "other states" are legally insufficient to confer standing upon named plaintiffs. *See In re Packaged Ice Antitrust Litig.*, No. 08-MD-01925, 2011 WL 891169, at \*12 (E.D. Mich. Mar. 11, 2011). Plaintiffs "are not suing derivatively for alleged injury to their members -- they are asserting claims on their own behalf for the damages they allegedly suffered." *In re K-Dur Antitrust Litig.*, MDL No. 1419, 2008 WL 2660783, at \*5 (D.N.J. Mar. 19, 2008). Accordingly, plaintiffs' state law claims except those alleged to arise under Illinois, Florida, and Pennsylvania law must be dismissed for lack of standing.

### IV. PLAINTIFFS' STATE LAW CLAIMS SUFFER FROM A MYRIAD OF LEGAL DEFICIENCIES REQUIRING DISMISSAL

If all the state law claims of Count II and Count III are not dismissed for the reasons set forth above, the Court should dismiss certain portions of the claims for the reasons set forth below.<sup>6</sup>

### A. Nine States' Consumer Protection Laws Do Not Reach the Plaintiffs' Claims Because Those Laws Only Cover Deceptive Conduct to Consumers

The consumer protection laws of Arizona, Colorado, Idaho, Michigan, Nevada, New Mexico, New York, South Dakota, and Tennessee do not apply to antitrust violations or similar anticompetitive conduct.<sup>7</sup> Rather, these laws only apply to conduct that constitutes a *fraud upon* 

<sup>&</sup>lt;sup>6</sup> For the Court's ease of reference, a chart indicating the bases for dismissing specific state law claims is attached as Exhibit A.

<sup>&</sup>lt;sup>7</sup> See In re New Motor Vehicles Canadian Export Antitrust Litig., 350 F. Supp. 2d 160, 178 (D. Me. 2004) (stating that the Arizona consumer protection statute "does not include a prohibition on unfair methods of competition" and dismissing indirect purchasers' claims for lack of deception); *Rhino Linings USA, Inc. v. Rocky Mountain Rhino Lining, Inc.*, 62 P.3d 143,

consumers. But there are no allegations in the Complaint that any defendant engaged in any communications with consumers or perpetrated any acts of deception that consumers relied upon. There is no allegation that any consumer relied upon any act or statement of any defendant at all. Accordingly, all claims under the laws of these states are baseless and should be dismissed.

Arizona. Allegations of bad faith conduct before federal regulatory agencies do not state a claim under the Arizona Consumer Fraud Act. In *Sheet Metal Workers Local 441 Health & Welfare Plan. v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380 (E.D. Pa. 2010), the court dismissed claims where plaintiffs alleged that the defendant had "made objectively baseless legal arguments in its patent infringement suits and misstatements to the PTO," but had not "misrepresented the nature or price of its product to consumers." *Id.* at 404. Accordingly the Arizona Consumer Fraud Act claim must be dismissed from Count II.<sup>8</sup>

Colorado. To recover under the Colorado Act, a plaintiff must allege a deceptive trade practice, which requires "proof that a defendant knowingly made a misrepresentation that induces a party's action or inaction." *Rhino Linings USA, Inc. v. Rocky Mountain Rhino Lining, Inc.*, 62 P.3d 143m 147-48 (Colo. 2003). The Complaint contains no allegations of deceptive conduct provoking reliance by any Colorado plaintiff; accordingly, this claim also must be

cannot provide the basis for a claim arising from anticompetitive conduct).

<sup>144 (</sup>Colo. 2003) (interpreting the Colorado Consumer Protection Act's prohibition on deceptive or unfair trade practices to require misrepresentations intending to induce consume reliance); Mich. Comp. Laws Ann. § 445.903 (specifically enumerating actions that are subject to the statute and not including anticompetitive acts); *State v. Daicel Chem. Indus., Ltd.,* 141 Idaho 102, 107–08 (2005) (declining to construe the Idaho Consumer Protection Act to cover price fixing); *Sherwood v. Microsoft Corp.,* No. M2000-01850-COA-R9-CV, 2003 WL 21780975, \*31-33 (Tenn. Ct. App. July 31, 2003) (holding that the Tennessee consumer protection act

<sup>&</sup>lt;sup>8</sup> Plaintiffs' alleged claim of violation of the Arizona Constitution must also be dismissed from Count II, as there is no separate claim under that state's constitutional provision. *See Bunker's Glass Co. v. Pilkington*, 202 Ariz. 481, 486 (Ariz. App. Div. 2002).

dismissed from Count II. *See Sheet Metal Workers*, 737 F. Supp. 2d. at 408 & n.12 (finding that allegations of false statements to the PTO did not state a deceptive trade practice aimed at consumers); *see also In re New Motor Vehicles Canadian Export Litig.*, 350 F. Supp. 2d 160, 167, 180 (D. Me. 2004).

<u>Idaho.</u> To state a claim under the Idaho Consumer Protection Act, plaintiffs must allege deceptive or unconscionable conduct that fits within the Act's preclusions. But plaintiffs have failed to do so. In *Sheet Metal Workers*, the court ruled that allegations regarding sham patent litigation are not encompassed by the Act, which applies to "unconscionable sales conduct directed at consumers," 737 F. Supp. 2d at 411. The court specifically ruled that the Act does not prohibit conduct which, "though generally deceptive, was not aimed at consumers, but rather was aimed at the PTO and other drug manufacturers." *Id*.

Michigan. "[I]t has long been the law that to constitute actionable fraud [under the Michigan Consumer Protection Act], a plaintiff must have 'suffered injury' as a result of his reliance on the defendant's false representation." *Mayhall v. A.H. Pond. Co., Inc.*, 341 N.W.2d 268, 270 (Mich. Ct. App. 1983); *see also New Motor Vehicles*, 350 F. Supp. 2d at 167, 189. There are no allegations that consumers within Michigan were deceived by defendants' representations or relied upon any alleged deceptive statement. Accordingly, this claim must be dismissed from Count II. *See Sheet Metal Workers*, 737 F. Supp. 2d at 413 (dismissing purported Michigan Consumer Protection Act claim based on sham litigation absent allegations of misrepresentations to plaintiffs and plaintiffs' reliance upon them).

Nevada. The Nevada Deceptive Trade Practices Act prohibits "deceptive trade practices," which are specifically identified acts that exploit unwitting consumers. *See*, *e.g.*, Nev. Rev. Stat. § 598.0915(9) (prohibiting bait and switch); Nev. Rev. Stat. § 598.50918(1)

(prohibiting threatening and abusive behavior in phone solicitations). Plaintiffs make no such allegations. Accordingly, this claim must be dismissed from Count II. Additionally, plaintiffs allege that there are "thousands" of class members, "many of them elderly" within Nevada. Compl. ¶ 140. The Nevada statute, however, limits potential plaintiffs *only* to "an elderly person or a person with a disability." Nev. Rev. Stat. § 598.0977. Plaintiffs' claims must be dismissed to the extent that plaintiffs seek recovery for claimants other than the elderly or disabled.

New Mexico. A claim under the New Mexico Unfair Practices Act requires a misrepresentation to be made in connection with a sale or other similar transaction. *Stevenson v. Louis Dreyfus Corp.*, 811 P.2d 1308, 1311 (N.M. 1991); *Brooks v. Norwest Corp.*, 103 P.3d 39, 51 (N.M. App. 2004); *Dellaira v. Farmers Ins. Exch.*, 102 P.3d 111, 117 (N.M. App. 2004). No such allegations are made here. Plaintiffs' single-word allegation that defendants' conduct has been "unconscionable," Compl. ¶ 116, without any further elaboration does not remedy this pleading defect.

New York. The same outcome is required under New York's Deceptive Acts and Practices Law. For liability to adhere, a deceptive act must be targeted at consumers, not at a federal agency or a competitor. *See Stutman v. Chemical Bank*, 95 N.Y.2d 24, 29 (N.Y. 2000) ("A plaintiff under section 349 must prove three elements: first, that the challenged act or practice was consumer-oriented; second, that it was misleading in a material way; and third, that the plaintiff suffered injury as a result of the deceptive act."); *Oswego Laborers' Local 214*Pension Fund v. Marine Midland Bank, N.A., 647 N.E.2d 741, 744-45 (N.Y. 1995). Courts have dismissed indirect purchaser claims purporting to arise under this statute where plaintiffs have failed to allege such conduct. *See Sheet Metal Workers*, 737 F. Supp. 2d at 418 (stating that even if defendants' alleged actions were "designed to prevent the consumer public's access to a less-

expensive form" of a drug, and such "actions were, at some level, deceitful, and they also eventually affected consumers, the disconnect between any deception and consumers . . . is simply too great to state a claim"); *see also Wellbutrin XL Antitrust Litig*, 260 F.R.D. at 164-65 (dismissing sham patent litigation and citizen petition claims).

South Dakota. General statements that defendants have been deceptive also are insufficient to state a claim under South Dakota's Deceptive Trade Practices and Consumer Protection Law; rather, the deceptive acts must be made "in connection with the sale or advertisement." S.D.C.L. § 37-24-6(1). Further, such claims "require proof of an intentional misrepresentation or concealment of a fact on which plaintiff relied and that caused an injury to plaintiff." *Nw. Pub. Serv. v. Union Carbide Corp.*, 236 F. Supp. 2d 966, 973-74 (D.S.D. 2002). *See also In re Pharmaceutical Ind. Average Wholesale Price Litig.*, 252 F.R.D. 83 (D. Mass. 2008) (plaintiffs must prove reliance); *Nygaard v. Sioux Valley Hospitals & Health Syst.*, 731 N.W.2d 184, 197 (S.D. 2007) (dismissing hospital patients' deceptive trade practices claim because they did not rely on defendants' alleged misrepresentations). Because plaintiffs do not allege that the defendants committed any deceptive act "in connection with the sale or advertisement" of DDAVP tablets, and because there are no claims of reliance by any South Dakota purchaser on any statement by a defendant, this claim must be dismissed from Count II.

Tennessee. The Tennessee Consumer Protection Act does not apply to antitrust claims. See Bennett v. Visa U.S.A., 198 S.W.3d 747, 754 (Tenn. Ct. App. 2006) ("the TCPA does not apply to anti-competitive conduct"). Therefore, this claim must also be dismissed from Count II.

### B. Failure to Allege Intrastate Effects Requires Dismissal of Claims Brought Under the Antitrust Laws of Mississippi, New Hampshire, North Carolina.

The antitrust laws of Mississippi, New Hampshire, and North Carolina all require that a specific anticompetitive act *within each state* be alleged. The Complaint does not do so.

Mississippi. The Mississippi Antitrust Act applies to combinations or conspiracies that have as their object a monopoly in *intrastate* trade and/or that are accomplished by *intrastate* transactions. *See Standard Oil Co. v. State ex rel. Att'y Gen.*, 65 So. 468, 471 (Miss. 1914), overruled in part, on other grounds, Mladinich v. Kohn, 164 So. 2d 785 (Miss. 1964). In Carder v. BASF Corp., 919 So. 2d 258, 260 (Miss. Ct. App. 2005), plaintiffs alleged an international conspiracy to fix prices for bulk chemical vitamins. The court dismissed the complaint, holding that the plaintiffs had alleged "an interstate and international conspiracy," rather than an intrastate conspiracy. *Id.* Similarly, the court in *In re Microsoft Corporation Antitrust Litigation*, MDL No. 1332, 2003 WL 22070561, at \*2 (D. Md. Aug. 22, 2003), rejected a claim under the Mississippi Antitrust Act because "[p]laintiffs . . . failed to allege . . . that this monopoly was to be accomplished by any transactions 'lying wholly within the state.'" Plaintiffs' allegations in the revised Complaint that putative class members "paid substantially higher prices for DDAVP within Mississippi," Compl. ¶ 140, fails to meet this standard.

New Hampshire. The New Hampshire Consumer Protection Act applies only to "trade or commerce within this state" (N.H. Rev. Stat. Ann. § 358-A:2), and courts have held that this language means that "commercial conduct which affects the people of New Hampshire is actionable under section 358-A:2 only if it occurs within New Hampshire." *Mueller Co. v. U.S. Pipe & Foundry Co.*, No. 03-170-JD, 2003 WL 22272135, at \*6 (D.N.H. Oct. 2, 2003) (dismissing NHCPA claim). There are no allegations that any consumer within New Hampshire was affected by the alleged conspiracy.

North Carolina. North Carolina's antitrust and unfair competition law applies only to "trade or commerce in the state of North Carolina." N.C. Gen. Stat. § 75-2.1. In *Sheet Metal Workers*, plaintiffs met this burden by alleging that the defendant "engaged in business in North Carolina by producing a drug sold and promoted in that state and . . . unlawfully maintained its monopoly in North Carolina." 737 F. Supp. 2d at 400. There are no such allegations here regarding any effects within North Carolina.

### C. Plaintiffs' Class Claims Are Not Permitted Under the Tennessee Consumer Protection Act ("TCPA")

The law providing for consumer protection suits in Tennessee does not allow for class actions; it only authorizes individual actions. Tenn. Code Ann § 47-18-101, *et seq.*; *Bearden v. Honeywell Int'l Inc.*, No. 3:09-1035, 2010 WL 3239285, at \*10 (M.D. Tenn. Aug. 16, 2010) ("The very statutory provision that authorizes a private right of action for a violation of the [TCPA] limits such claims to those brought 'individually.""). Accordingly, to the extent that Plaintiffs seek class action relief under Tennessee law, those claims must be dismissed. 9

#### D. Plaintiffs' Unjust Enrichment Claims Must Be Dismissed

In addition to the reasons set forth above, plaintiffs' unjust enrichment claims should be dismissed where such claims: (1) conflict with that state's limitations on indirect purchaser antitrust suits; (2) do not allege the direct provision of a benefit from plaintiff to defendant; and/or (3) do not provide an independent basis for relief when no other legal violation is alleged.

<sup>&</sup>lt;sup>9</sup> The Supreme Court's recent decision in *Shady Grove Orthopedic Associates, P.S. v. Allstate Insurance Co.*, 130 S. Ct. 1431 (2010) does not change this outcome. *Shady Grove* merely holds that a separate state *procedural* rule cannot preclude a federal class action where the substantive state law is not limited to individual actions. In contrast, the Tennessee limitation on who may recover is contained in the substantive provision that authorizes a private right of action itself. *See Bearden v. Honeywell*, 2010 WL 3239285, at \*10 (M.D. Tenn. 2010) (holding that the Tennessee limitation of recovery to individuals applied in federal court).

The unjust enrichment claims for the states of Alaska, Colorado, Connecticut, Delaware, Indiana, Kentucky, Louisiana, Maryland, Missouri, New Jersey, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, and Texas must be dismissed because those jurisdictions prohibit indirect purchasers from recovering under their state antitrust or consumer protection law. Allowing plaintiffs to recover under unjust enrichment claims in these jurisdictions would constitute an end-run around those states' statutory and judicial limitations on indirect purchaser suits, and courts have repeatedly dismissed indirect purchaser unjust enrichment claims for this reason. See, e.g., Sheet Metal Workers, 737 F. Supp. 2d at 424; New Motor Vehicles, 350 F. Supp. 2d at 211-12 ("For those states that have maintained the *Illinois Brick* prohibition on indirect purchaser recovery, . . . it would subvert the statutory scheme to allow these same indirect purchasers to secure, for the statutory violation, restitutionary relief at common law."); In re Terazosin, 160 F. Supp. 2d at 1380 ("The end payors' unjust enrichment claim raises identical concerns" to those stated in *Illinois Brick*. "State legislatures and courts that adopted the *Illinois Brick* rule against indirect purchaser antitrust suits did not intend to allow an end run around the policies allowing only direct purchasers to recover.").

Furthermore, in the states of Florida, Idaho, New York, and North Dakota, for unjust enrichment to be available, plaintiffs must allege that the plaintiff gave a direct benefit to the defendant. *See In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 544 (E.D. Pa. 2010) (Florida law "requires that a plaintiff confer a direct benefit upon a defendant in order to state a claim for unjust enrichment" (citing *Nova Info. Sys., Inc. v. Greenwich Ins. Co.*, 365 F.3d 996, 1007 (11th Cir. 2004)); *Sheet Metal Workers*, 263 F.R.D.at 216 (summarizing cases where New York state courts found relationships "too attenuated" to support unjust enrichment claims and dismissing indirect purchasers' unjust enrichment claims on this ground); *Hayden Lake Fire Prot. Dist. v.* 

Alcorn, 111 P.3d 73, 91-92 (Idaho 2005) (affirming district court's dismissal of unjust enrichment claim because there was no direct benefit); Apache Corp. v. MDU Resources Group, Inc., 603 N.W.2d 891, 895 (N.D. 1999) (stating recovery for unjust enrichment claims under North Dakota law requires one to "obtain a benefit at the direct expense" of another); TFT-LCD (Flat Panel) Antitrust Litig., 599 F. Supp. 2d 1179, 1190-91 (N.D. Cal. 2009) (applying Apache to dismiss indirect purchasers' unjust enrichment claims under North Dakota law).

Courts have repeatedly held that the direct benefit rule precludes recovery by indirect purchasers. *See, e.g., Flonase Antitrust Litig.*, 692 F. Supp. at 545 (dismissing indirect purchasers' unjust enrichment claim because Florida law requires that a "plaintiff confer a direct benefit upon a defendant"); *Sheet Metal Workers*, 737 F. Supp. 2d at 411. Because the indirect purchaser plaintiffs did not confer a benefit directly on defendants, their unjust enrichment claims must be dismissed.

Finally, courts have refused to permit state "unjust enrichment" claims to proceed when there is no other state law basis for the relief sought by the plaintiff. Accordingly, courts have dismissed "unjust enrichment" claims in conjunction with their dismissal of plaintiffs' state antitrust or consumer protection claims. If plaintiffs are not entitled to pursue a state antitrust or consumer protection claim against defendants here, they should not be permitted to concoct a claim out of the ethereal law of "unjust enrichment." *See Sheet Metal Workers*, 737 F. Supp. 2d at 427-48 (dismissing the unjust enrichment claims under multiple states in which the court also dismissed the antitrust or consumer protection claim); *Flonase Antitrust Litig.*, 692 F. Supp. 2d at 532 ("where an antitrust defendant's conduct cannot give rise to liability under state antitrust and consumer protection laws, Plaintiffs should be prohibited from recovery under a claim for unjust

enrichment"); and *New Motor Vehicle*, 350 F. Supp. 2d at 210 (dismissing all freestanding unjust enrichment claims).

#### **CONCLUSION**

For the foregoing reasons, defendants respectfully request the Court to dismiss the plaintiffs' Amended Consolidated Class Action Complaint under Fed. R. Civ. P. 12(b)(1) and 12(b)(6).

Dated: September 16, 2011

Respectfully submitted,

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